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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,430	09/19/2006	Yoon Jeong Park	4240-149	7380

23448 7590 02/03/2009

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
KEMMERER, ELIZABETH	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,430	PARK ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *2,3,11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10 and 13-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of SEQ ID NO: 6, organism-derived bone mineral powders, and sulfo-SMCC in the reply filed on 09 October 2008 is acknowledged. The traversal is on the ground(s) that all of the species share a special technical feature and thus should be examined together. Applicant takes issue with Puleo et al., arguing that Puleo is limited to full-length BMP-4 whereas elected SEQ ID NO: 6 is a specific fragment. This is not found persuasive because the generic claim, claim 1, recites a cell adhesion-inducing peptide and/or tissue growth factor-derived peptide. Puleo clearly teaches this. Therefore, claim 1 does not have a special technical feature as defined by the PCT rules, and a requirement to elect a species was proper.

Regarding the species of Parts II and III, Applicant argues that the species share a technical relationship. While this argument was not entirely persuasive, upon further consideration and a review of the prior art the requirement to elect a species from Parts II and III is *withdrawn*. The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 3, 11, and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09 October 2008.

Status of Application, Amendments, And/Or Claims

The preliminary amendment of 19 September 2006 is entered in full. Claims 2, 3, 11, and 12 are withdrawn from consideration, as discussed above. Claims 1, 4-10, and 13-22 are under examination to the extent they read on the elected invention.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 19 September 2006 has been received and entered into the file. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The disclosure is objected to because of the following informalities: The text of the specification discusses specific fragments of specific BMP proteins, and then refers to a sequence identifier (i.e., SEQ ID NO:) for each fragment. However, there is a lack of correspondence between the discussion of the fragments and the sequences appearing in the sequence listing. For example, Applicant elected SEQ ID NO: 6, which is derived from BMP-2 and is 16 amino acids in length according to the sequence listing. However, the specification indicates that SEQ ID NO: 6 corresponds to residues 16-34 of BMP-2 (see, for example, p. 4 of the specification), which is 19 amino acids in length. Appropriate correction is required. New matter must be avoided.

Claim Objections

Claims 1, 5, 10, and 14 are objected to because of the following informalities: Claims 1 and 10 have a typographical error wherein "have" should be "has" in order to be grammatically correct. Similarly, claims 5 and 14 should have "the" inserted before "N-terminal end." Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant elected SEQ ID NO: 6, which is derived from BMP-2 and is 16 amino acids in length according to the sequence listing. However, the claims indicate that SEQ ID NO: 6 corresponds to residues 16-34 of BMP-2. Residues 16-34 is 19 amino acids in length. Therefore, it is unclear which sequence is intended.

Priority

Applicant's claim for priority to Korean document 10-2004-0019010, filed 19 March 2004 is noted, and the certified copy of this document was received on 19 September 2006. The document is in the Korean language, and thus only a limited review of this document could be accomplished. However, it was clear that the

sequence listing of the document did not list the elected sequence, SEQ ID NO: 6. Similarly, the specification did not appear to refer to residues 16-34 of any sequence, or any sequence that was 16 amino acids in length. Therefore, priority is denied to Korean document 10-2004-0019010, filed 19 March 2004. The effective filing date of the instant application is determined to be that of the PCT/KR05/00801 document, 18 March 2005.

WO 2005/113585, cited below, qualifies as prior art under 35 U.S.C. § 102(e) for the following reasons. '585 was published on 11 December 2005 in English and designated the United States of America. The international filing date of '585 is 20 May 2005. '585 claims priority to an earlier effective U.S. filing date of 20 May 2004 from provisional application 60/573,718. According to M.P.E.P. 901.03, a WIPO publication of an international application under PCT Article 21(2) is considered to be prior art under 35 U.S.C. 102(e) as of the international filing date, or an earlier effective U.S. filing date, only if the application was filed on or after 29 November 2000, designated the United States, and was published under PCT Article 21(2) in English. Since all of these requirements are met, '585 qualifies as prior art by virtue of its earlier effective U.S. filing date, 20 May 2004.

35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 7, 10, 13, 16, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **US 6,409,764 B1** (White et al.; issued 25 June 2002) in view of **WO 2005/113585 A2** (Acceleron Pharma Inc.; published in English 11 December 2005; international filing date 20 May 2005 designating the US; earlier effective US filing date 20 May 2004).

'764 teaches a bone graft material or scaffold for tissue engineering applications comprising BMP-2 immobilized on the surface. The material is a biocompatible polymer

that is porous. See col. 24-27, Example 2. See especially col. 25, lines 24--49, treatment (iii). '764 also teaches membranes made of polylactic acid. See col. 14, lines 46-54. '764 does not teach immobilizing a fragment of BMP-2, namely, elected SEQ ID NO: 6. However, '585 teaches exactly this fragment at p. 20, line 4.

Therefore, given that the level of skill in the medical arts is very high and in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the material of '764 by using the BMP-2 fragment disclosed by '585 with a reasonable expectation of success. As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. *KSR,* 127 S. Ct. at 1740. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82USPQ2d 1385, 1396 (2007).

Claims 5, 6, 8, 9, 14, 15, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over **US 6,409,764 B1** (White et al.; issued 25 June 2002) in view of **WO 2005/113585 A2** (Acceleron Pharma Inc.; published in English 11 December 2005; international filing date 20 May 2005 designating the US; earlier effective US filing date

20 May 2004) as applied to claims 1, 4, 7, 10, 13, 16, and 17 above, and further in view of **Gauvreau et al.** (2004, Bioconjugate Chem. 15:1146-1156) and **US 6,316,003 B1** (Frankel et al.; issued 13 November 2001).

As discussed above, '764 teaches a bone graft material or scaffold for tissue engineering applications comprising BMP-2 immobilized on the surface, and '585 teaches the elected BMP-2 fragment, SEQ ID NO: 6.

'764 does not teach the addition of cysteine, such as a CGG spacer, at the N-terminal end of the BMP-2 protein or fragment, the use of a cross-linker such as sulfo-SMCC to immobilize the peptide on the solid support, or oxidation and nitrification to facilitate adhesion of peptides to the surface of the solid support. However, this method was known. Specifically, Gauvreau et al. discusses the use of sulfo-SMCC to achieve cross-linking of a cysteine-containing protein to a solid substrate in order to immobilize the protein. Gauvreau et al. also teach oxidation and nitrification to facilitate adhesion of proteins to solid supports. '003 teaches the addition of CGG to the N-terminus of a tat protein fragment that lacked a cysteine, and the use of sulfo-SMCC modified ribonuclease to achieve a cross-linking reaction. See col. 32, lines 36-61.

Therefore, given that the level of skill in the medical arts is very high and in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the material of '764 by using the BMP-2 fragment disclosed by '585 and the CGG-linker/sulfo-SMCC system for cross-linking as suggested by Gauvreau et al. and '003 with a reasonable expectation of success.

This is because known work in one field of endeavor was known to prompt variations of it for use in the same field to achieve predictable results.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over **US 6,409,764 B1** (White et al.; issued 25 June 2002) in view of **WO 2005/113585 A2** (Acceleron Pharma Inc.; published in English 11 December 2005; international filing date 20 May 2005 designating the US; earlier effective US filing date 20 May 2004) as applied to claims 1, 4, 7, 10, 13, 16, and 17 above, and further in view of **Puleo et al.** (2002, Biomaterials 23:2079-2087)

As discussed above, '764 teaches a bone graft material or scaffold for tissue engineering applications comprising BMP-2 immobilized on the surface, and '585 teaches the elected BMP-2 fragment, SEQ ID NO: 6.

'764 does not teach the use of titanium implant materials. However, such was known in the prior art. For example, Puleo et al. teaches a titanium implant on which was cross-linked BMP-4 for the purpose of developing orthopedic and dental implants that induced bone formation.

Therefore, given that the level of skill in the medical arts is very high and in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the material of '764 by using the BMP-2 fragment disclosed by '585 and the titanium implant material as suggested by Puleo et al. with a reasonable expectation of success. This is because known work in one field

of endeavor was known to prompt variations of it for use in the same field to achieve predictable results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ECK/
01 February 2009

/Elizabeth C. Kemmerer/
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